breastlight™
enlightened breast awareness

Presentation to:
FDA, HHS:
Radiological Devices Panel of the Medical Devices Advisory Committee Meeting.
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PWB Health Ltd – Manufacturer of the Breastlight.

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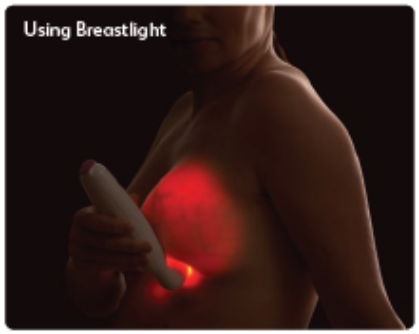

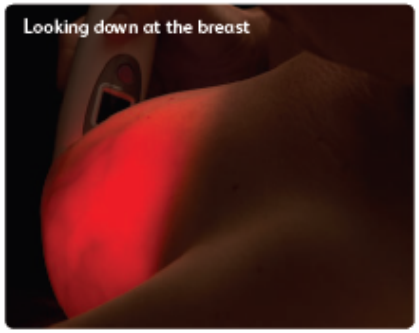

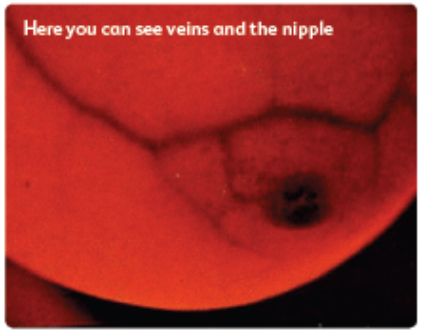

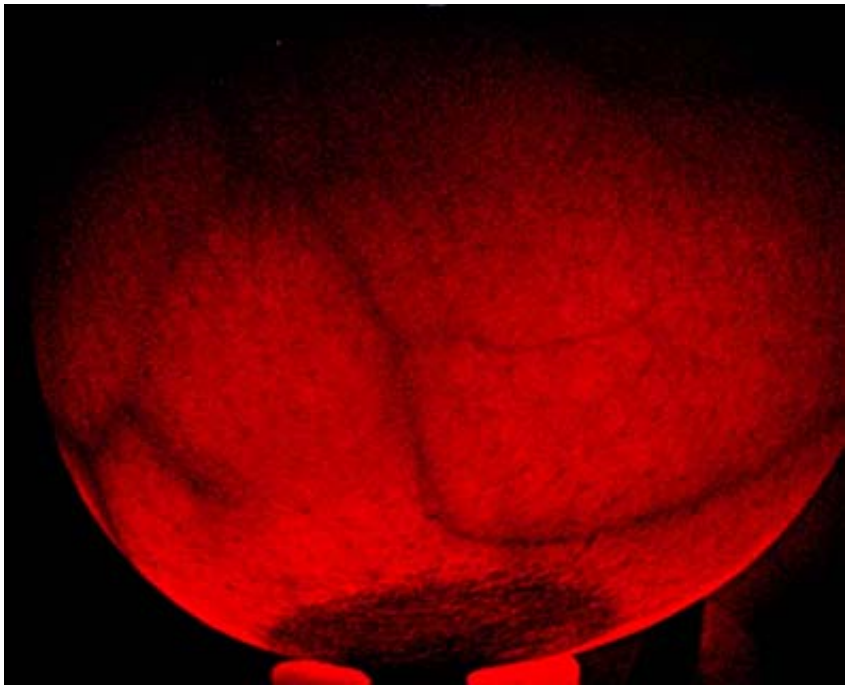

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Background: - Breastlight – Domestic Breast Transilluminator.

- Breastlight product launched by PWB Health in July 2008
- Intended use: A home-use aid to Breast Awareness / Breast Self Examination**"..*as an additional part of your normal breast awareness routine.*"**
- Currently sold in UK, Europe, Middle East, Africa, China and others
- Class 1 Medical device
- Designed to be:
    - Low cost product
    - Non Diagnostic product
    - Simple to use for home use
    - Safe and effective.
- 28,000 products sold
- Users encouraged to register their experience at PWB web site
- Three studies completed as part of post marketing surveillance.

Conclusion:

Breastlight encourages a greater proportion of women to check their breasts on a more regular basis and provides additional reassurance to women. Fears of false reassurance or over reliance on Breastlight not founded.

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Initial dialogue with FDA (Obstetrics and Gynaecology Devices Panel) about breast transilluminators highlighted potential concerns:

- Electrical Shock Risk
- Optical Radiation Risk
- Potential for missed or delayed diagnosis (false reassurance or false negative) or unnecessary anxiety from false positive.

PWB Health risk assessment (ISO 14971) already identified and addressed these potential risks:

-Electrical Shock Risk – low power, low voltage product (9 volts) complies with ISO 60601 – EMC, ESD, Low Voltage Directive.

- Optical radiation risk – 617nm wavelength – eye safe at maximum power setting. Tested as Class 1 LED product to IEC / EN 60825-1. Additional patented feature of capacitive switch – only allows full light output when in full contact with the skin.

- Potential for missed or delayed diagnosis or false positives –IFU, DVD and packaging appropriate to potential misuse. Three studies completed quantify the benefits of breastlight use and indicate no evidence of false reassurance or unnecessary anxiety.

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First Study – UK 2007/2008 – 1087 users.

- Womans Institute and Nurse study.
- Home use using Breastlight, IFU and DVD.
- Questionnaire completed before and after using Breastlight
- Results collated from 1087 users.

Key findings:

- Current IFU, DVD and packaging convey an appropriate level of caution in interpretation of the results.
-33% increase in Breast Awareness / Breast Self examination frequency as a result of use of the Breastlight.
- 4% of users saw something abnormal, most consulted a doctor or nurse.
- 3 had mammogram, 1 user (out of 1087) detected a previously undiagnosed, non-palpable, breast cancer.
-Increased confidence in self checking.

Follow Ups:

- DVD of Breastlight in use added to all products.
- DVD and IFU added more information on what to look for.
- IFU improved with additional information (skin colour, lubricant use)
- Data reviewed and presented by Mr. Jayant Vaidya, Consultant Surgeon, Research Dept. of Surgery, University College London (presentation also circulated).

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Second Study – UK 2009 – 300 patients.

-“A Clinical Investigation to Develop an Evidence Base for the use of Breastlight™ in examining the Breast”.
- Mr. Obi Iwuchukwu, Breast Surgeon, Sunderland Royal Hospital
- Ethics committee approval not straightforward.
- Study agreed was 300 women in a referral clinic.
- Breastlight used before woman goes through standard care.
- Breastlight results compared to final diagnosis.

Key findings:

-Breastlight performs well against cytological/histological findings; 12 of 18 malignant tumours were detected using Breastlight giving a sensitivity of 67% (95% confidence interval 41% to 87%). 240 of 282 breasts with no malignancy found were correctly identified as negative giving a specificity of 85% (95% confidence interval 80% to 89%). *(see page 22)*

Follow Ups:

Results published in proceedings of Milan Breast Cancer Conference July 2010.
The results reinforce our view that Breastlight is not a suitable alternative to X Ray mammography but is a useful addition to breast awareness / self examination.

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Third Study – UK 2009 / 2010 – 53 patients.

- Some health professionals concerned about potential for false reassurance or anxiety in using the product – independent study arranged to address this concern.
- Edinburgh Napier University study / Ethics committee approved.
-Breastlight users asked to keep a diary of use and observations over 6 months
- Questionnaire completed before and after use.

Key findings:

-“The breastlight was found by 50% of women who completed the study to be a valuable addition to their breast health routine, and increased their confidence levels when being breast aware”.
-“There was no evidence that using the Breastlight caused significant distress among the participants”

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Benefits of Breastlight:

- Increase in confidence in women carrying out Breast Self Examination.
- Increase in Breast Self Examination frequency.
- Women more likely to seek a medical opinion using Breastlight.

Breastlight may have particular applicability for:

-Women with naturally lumpy / fibrous breasts – (Breastlight shines through)
-Checking for interval cancers between regularly scheduled X ray mammography
-Women with higher anxiety towards breast cancer – perhaps due to a family history of breast cancer
-Encouraging women to be more breast aware / carry out breast self examination.
-Providing additional information to women thus allowing a more open and informed discussion with healthcare professionals.

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Recommendations to the committee:

•Benefits of the Breastlight clearly outweigh perceived risk.
•With appropriate safeguards in place Breastlight should be made available as an aid to Breast Self Examination.
•Re classification as a Class 1 medical device.

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Thank you for listening.

Any Questions?